



March 23, 2009

Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, VA 22152

Attention: DEA Federal Register Representative/ODL

The New England Interstate Water Pollution Control Commission (NEIWPCC), on behalf of the New England states and New York, respectfully submits the following comments on *Docket No. DEA-316: Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration.* These comments were developed through the input of our Pharmaceuticals and Personal Care Products (PPCP) Workgroup to ensure representation of NEIWPCC Compact Member states' views and opinions. NEIWPCC's role is to coordinate and assist the efforts of our seven member states to improve and maintain water quality. NEIWPCC is committed to maintaining the health of aquatic environments and ecosystems, and the PPCP Workgroup is concerned by the threats posed by the misdirected and unnecessary disposal of pharmaceuticals.

We recognize the need for a better approach for handling the disposal of dispensed controlled substances by ultimate users, and we are grateful for the DEA's recognition of this issue and the opportunity to comment. The unintended environmental consequences associated with historic disposal practices have recently come to light, and we agree that there is a need to reevaluate our regulations. The problems associated with the handling and disposal of unused or unwanted pharmaceuticals, both controlled and non-controlled substances, are well documented; there are numerous occurrences of purposeful diversions, accidental poisonings, and the degradation of our nation's waters. Aquatic ecosystems are bearing the load of substances disposed of via conventional methods, i.e., flushing. Numerous published studies have revealed detectable concentrations of pharmaceuticals in our nation's waterways. There are also documented impacts to aquatic organisms from exposure to compounds such as endocrine disruptors.

Recent discoveries of pharmaceuticals in a number of our nation's public water supplies have raised questions regarding potential public health impacts. In some areas of New England, we are aware of instances where long-term health care facilities and hospices dispose of large volumes of controlled substances into municipal sewers or onsite wastewater (septic) systems. In some cases, private drinking water wells are located within 500 feet of these septic systems, indicating a potential risk for controlled substances to enter water supplies as a direct result of the disposal practices.

Fostering Collaboration  
on Water Issues

Training Environmental  
Professionals

Coordinating  
Water Research

Educating  
the Public



116 John Street  
Lowell, Massachusetts  
01852-1124

mail@neiwpcc.org  
www.neiwpcc.org

p: 978-323-7929  
f: 978-323-7919

## Use Comments as a Starting Point

We strongly urge the DEA to take the comments received from all parties and use them to explore viable alternatives to the current controlled substance disposal framework. We are pleased to see that DEA recognizes that “the distribution of a controlled substance by an ultimate user for the purpose of disposal is a scenario not contemplated by the Controlled Substances Act (CSA) and its closed system of distribution” (pg. 3483) and is exploring opportunities to make beneficial changes. Taking the end user into account and allowing for environmentally sustainable disposal methods to be enacted is integral to addressing one of the pathways through which pharmaceuticals are entering the aquatic environment and impacting water quality.

## Separation and Simplification

We are recommending that the DEA change its ultimate user management regulations within the framework of the CSA and separate user types. We believe that the regulations should specifically describe methods for the disposal of controlled substances in each of the following settings:

- Residential
- Hospital with an in-house pharmacy
- Long-term health care facility (LTCF) without an in-house pharmacy
- Hospice and similar end-of-life facility
- Nursing office in educational or institutional facility

Each of these settings faces different issues and relies on different resources to deal with unused controlled substances. For example, it is likely that many prescription recipients are unaware of disposal techniques and restrictions surrounding controlled substances; they may not even know if medications are classified as controlled substances. Many LTCFs utilize consulting pharmacists who may or may not be available on-site. Hospitals, on the other hand, have in-house pharmacies and can dispense and control the management of controlled substances more appropriately. Hospices are generally staffed only by nurses, utilize a high volume of liquid controlled substances, and by the nature of the facility have a high patient turnover rate. This means a large volume of dispensed medications require disposal.

There are several possible avenues, already included within the CSA that the DEA could explore as disposal options for ultimate users.

- Reverse distributors that are DEA registrants are already entrusted by the DEA to responsibly receive and dispose of controlled and non-controlled substances. It is plausible to allow them to receive substances from ultimate users for the purpose of proper disposal.
- Pharmacists and pharmacies that are DEA registrants are already entrusted by the DEA to responsibly receive and distribute controlled and non-controlled substances as prescriptions to

ultimate users. It is conceivable that pharmacies could be used as regulated collection points for unused or unwanted medications for proper disposal.

- Some law enforcement agencies have been given permission from the DEA to oversee and facilitate take-back programs as deputies of the DEA. It would be feasible to standardize and simplify the deputization process so that take-back programs can more easily comply with state and federal regulations.
- Some hospitals have been DEA-inspected and are allowed to utilize secure drop boxes in patient rooms; these boxes are serviced by reverse distributor/waste management firms for proper disposal. Expanding this practice to more hospitals would be an easy and safe way to dispose of controlled substances in an institutional setting.
- Current regulations mandate that dispensed medicine be immediately destructed if it is not going to be used as prescribed. The DEA's regulations should identify methods for destruction that both protect the environment and prevent drug abuse and drug poisoning. For instance, using denaturing agents in drop boxes serviced by waste management or reverse distributor firms could be an option in certain settings.
- The DEA describes in detail its historic efforts to broaden dispensing options for controlled substances with the goal of waste reduction. Encouraging pharmacists and physicians to dispense substances more conservatively would reduce the amount of medication being discarded. The DEA should develop regulations that require audits of facilities that dispose of relatively high volumes of dispensed controlled substances. These audits would determine if a facility could feasibly amend and optimize its controlled substances prescription and dispensing practices to reduce the amount generated.

It is necessary for pharmaceutical regulations, written with public safety and security in mind, to be updated to account for these new methods of controlled substance disposal.

### Funding and Outreach

The issue of funding is also of great concern to our member states. It is important that the DEA recognize that many state programs are not in place or fully functioning due to the lack of federal funding to support pharmaceutical take-back programs and research. States are willing to take the lead on this issue, but funding would be necessary. There is great potential for states to research the effectiveness (and effects) of drug removal methods from households, hospitals, long-term care facilities, etc., if given the proper funding. It is also essential that all facilities involved with the dispensing and the disposing of controlled and non-controlled substances be better educated on appropriate medicine disposal practices. Funding for public (ultimate user) education and outreach is integral to the success of appropriate disposal practices for pharmaceuticals. It is also vital that

education focus on all the factors driving the need for proper disposal – protecting the public from accidental poisonings, reducing purposeful diversions, and minimizing the environmental impact.

### **Inter-Agency Collaboration**

It is also important that the DEA collaborates with its counterpart agencies such as the U.S. Environmental Protection Agency and the Food and Drug Administration to ensure consistent, compatible messages regarding proper controlled and non-controlled substance disposal methods. States are looking to federal agencies to play a bigger role in the issues surrounding pharmaceuticals. The adverse impacts of compartmentalized regulations on stakeholders – ranging from the ultimate user, to the state agency, to the aquatic ecosystems – must be recognized and addressed. A clear, simplified, and effective plan for facilitating drug disposal at the household and institutional scale is only achievable at the federal level with inter-agency cooperation and appropriate funding to support that effort.

NEIWPCC greatly appreciates your consideration of the comments and suggestions in this letter. We look forward to continuing this conversation with Drug Enforcement Administration staff in the future. If you have any questions, please do not hesitate to contact me or Sarah Peters of my staff at (978) 323-7929.

Sincerely,



Ronald F. Poltak  
Executive Director

Cc: NEIWPCC Executive Committee  
NEIWPCC Pharmaceuticals and Personal Care Products Workgroup  
Susan Sullivan, Rebecca Weidman, and Sarah Peters, NEIWPCC